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Tulsa, OK 74104

THE
EYE INSTITUTE

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January 3, 2000

Dockets Management Branch (HSA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket #97N-484S

To Whom It May Concern:

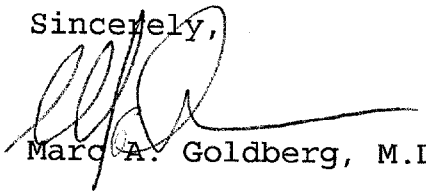
This letter is in support of the proposed Eye Bank Association of America's (EBAA) comments and suggestions for change regarding docket #97N-484S; suitability determination for donors of cellular- and tissue-based products; 64 Federal Register 189; September 30, 1999.

In the FDA's proposal, there is too broad a regulation of tissue. Corneal tissue is different from other transplantable tissue and should be considered separately from them. The cornea is an avascular organ, which sets it apart from almost every other transplantable tissue or organ. As noted in the agency's statement on page 52713 of the Federal Register, risks of disease transmission do vary by cellular- and tissue-based products.

I would ask you to consider the EBAA's comments seriously, and I sincerely hope that you will change your stance, at least with regard to corneal tissue.

Thank you for your time and consideration.

Sincerely,


Marc A. Goldberg, M.D./nb

97N 484S

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